AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
RICHTER, Jacob.	Examiner: Bradford C. Pantuck
Serial No: 09/878,749	
Filed: 11 June 2001	Art Unit: 3731
For: **TWO BALLOON STAGED STENT EXPANSION**	

APPEAL BRIEF under 37 CFR 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

ATTENTION: Board of Patent Appeals and Interferences

Sir:

Appellant submits this Appeal Brief in the above-referenced application. A Notice of Appeal was filed on August 18, 2005.

REAL PARTY IN INTEREST

Medinol, Ltd. is the real party in interest for all issues related to this application.

RELATED APPEALS OR INTERFERENCES

There are no other appeals, interferences, or judicial proceedings known to Appellant, appellant's legal representative, or Medinol, Ltd. which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

This application contains claims 1-12 and 22-32. Claim 13-21 are canceled. Claims 1-12 and 22-32 stand finally rejected as obvious over prior art and are the subject of this appeal.

STATUS OF AMENDMENTS

The claims were amended in an Amendment submitted on February 17, 2005 which was entered by the Examiner. There are no amendments that have not been entered.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is directed to a stent and balloon catheter in combination. As shown in Fig. 1 the catheter includes an inner balloon 6 and an outer balloon 8. The outer balloon 8 overlays the inner balloon 6. (page 3, lines 24-32). An expandable stent 14 is mounted over the inner and outer catheter balloons as shown in Fig. 1. The burst pressure of the inner balloon 6 is less than the burst pressure of the outer balloon 8. (page 4, line 32 to page 5, line 13). The length of the outer balloon 8 is greater than the length of the stent 14 (page 4, lines 1-3) and the length of the inner balloon 6 is less than the length of the stent (page 3, line. 27-29). The burst pressure of the inner balloon 6 is such that, when inflated with a pressurized medium it will expand sufficiently to expand the middle portion of the stent and implant the stent (page 4, lines 29-36).

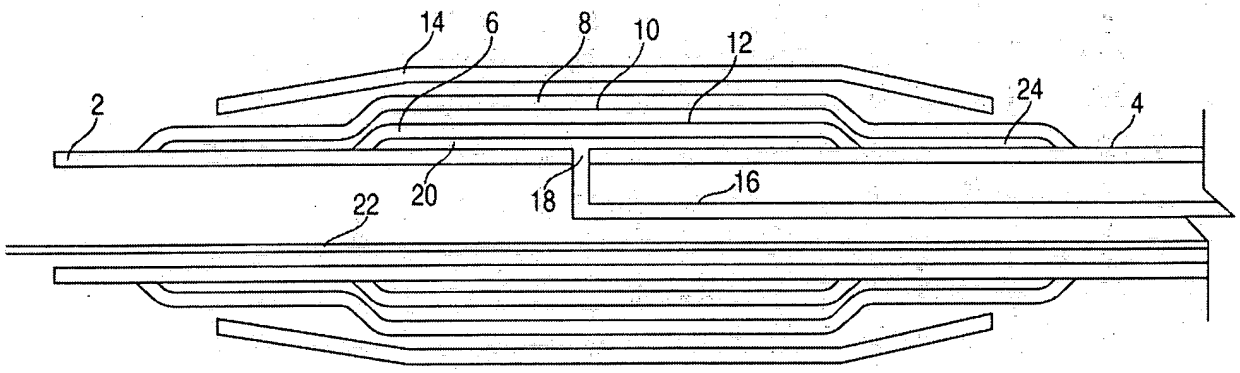


FIG.1

Independent claim 23 is also directed to a stent and balloon catheter in combination. It includes the features of claim 1 discussed above and include additional limitations as follows: Both said inner balloon 6 and said outer balloon8 are sealed to a catheter shaft 2 at each end (page 3, lines 25-27 and page 3, lines 35-36). An inflation lumen 16 in the catheter shaft is in communication only with the interior of the inner balloon 6 (page 4, lines 8-15). Pressurized

medium from the inflation lumen 16 can enter the interior of said outer balloon 8 to inflate it and further expand the stent over its full length only after said inner balloon 6 bursts (page 4, line 32 to page 5, line 8).

Claims 2 and 24, depending respectively on claims 1 and 23, define the burst pressure of the inner balloon to be less than 10 atmospheres and claims 3 and 25, depending respectively on claims 2 and 24, define the burst pressure of the inner balloon to be approximately 5 atmospheres (page 4, lines 34-36).

Claims 4 and 26 , depending respectively on claims 3 and 25, claim the burst pressure of the outer balloon to be greater than 10 atmospheres (original claim 4).

Claim 5 claims the burst pressure of the inner balloon to be approximately 5 atmospheres and claim 6 the burst pressure of the outer balloon to be greater than 10 atmospheres. Both depend on claim 1(page 5, lines 7-13 original claims 5 and 6).

Claims 7 and 27, depending respectively on claims 3 and 24, further define the outer balloon as being formed of a non-compliant material (page 3, line 36 to page 4, line 1).

Claims 8 and 28, depending respectively on claims 7 and 27 add that the inner balloon is formed of a non-compliant material (page 3, lines 29-30).

Claims 9 and 29, depending respectively on claims 1 and 23 also define the outer balloon being formed of a non-compliant material (page 3, line 36 to page 4, line 1).

Claims 10 and 30, depending respectively on claims 9 and 29 claim the inner balloon being formed of a non-compliant material (page 3, lines 29-30).

Claims 11 and 31 add to claims 1 and 23 the feature that the catheter shaft has a guidewire port located adjacent the balloons(page 4, lines 17-20) .

Claims 12 and 32, depending respectively on claims 1 and 23 define the burst pressure of the first balloon is at least 5 atmospheres less than the burst pressure of the second balloon (page 5, lines 7-13).

Claim 22 adds to the limitations of claim 1 the burst pressure of the outer balloon is such that, when inflated with a pressurized medium it will expand sufficiently to expand the entire length of the stent (page 5, lines 3-4).

GROUNDS OF REJECTION TO BE REVIEWED

The Final Rejection rejects claims 1-12 and 22-32 under 35 U.S.C. §103(a) as being unpatentable over Miller (USPN 5,358,487) in view of DiCaprio et al. (USPN 6,419,685).

ARGUMENT

A. Rejection of claims 1-12 and 22-32 under 35 U.S.C. §103 over Miller in view of DiCaprio et. al is improper.

1. Independent Claims 1 and 23 are allowable

In rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Further, the Examiner must not only identify the elements in the prior art, but also show some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead the individual to combine the relevant teachings of the references. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Such evidence is required in order to establish a *prima facie* case of obviousness. In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Appellant submits that the Examiner has failed to establish a *prima facie* case of obviousness in rejecting the claims on appeal.

The invention as claimed in claims 1 and 23 is directed to a structure that avoids dogboning[1], a problem not addressed in any of the references. The present invention does this, inter alia, by:

1. making the inner balloon shorter than the stent and the outer balloon longer than the stent ; and

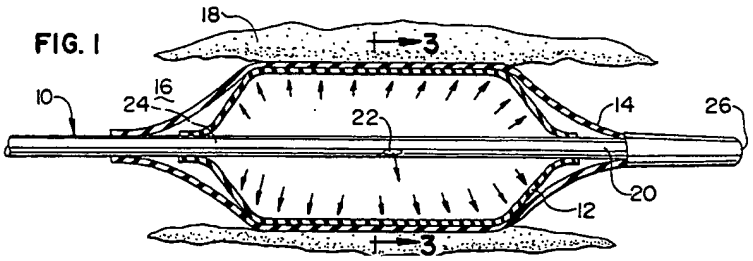
2. making the burst pressure of the inner balloon less that that of the outer balloon.

Through these provision, the inner balloon can be inflated and implant the central are of the stent in the vessel. It then bursts and the outer balloon inflates to expand the stent and implant the ends in such a manner that there is no dogboning.

In addition to not discussing the problem of dogboning, the references also do not suggest the claimed combination for that or any other reason. Further, even if one combined the references, there would still be elements of the claims missing.

Miller, as seen in Fig. 1 has inner balloon 12 and outer balloon 14 of equal length. There is no stent mounted on the balloons. The balloons are used for angioplasty. The outer balloon is capable of expansion to a greater diameter than the inner balloon. The inner balloon is inflated and expands to its full diameter and with additional pressure breaks, after which the outer balloon further expands. The advantage noted at Col. 4, lines 1-5 is that the physician can possibly avoid inserting a second balloon with a larger diameter after doing expansion with a smaller diameter balloon. Thus, although Miller has inner and outer balloons and the inner balloon bursts before the outer balloon allowing expansion of the outer balloon, it does not

FIG. 1



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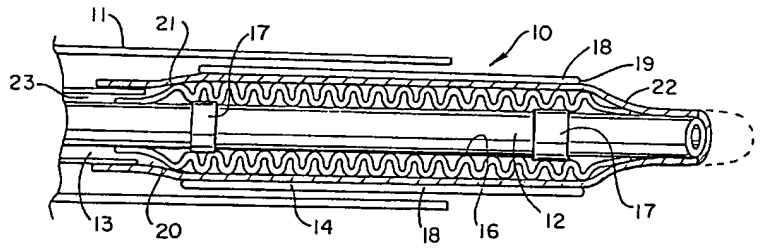
[1] "Dogboning" occurs when the ends of the stent expand more that the center part to cause the expanded stent to have a shape that is larger at the ends like a dog bone.

include a stent and does not have the required limitation of making the inner balloon shorter than the stent and the outer balloon longer than the stent.

In DiCaprio et al., the outer balloon 14, the only element actually called a balloon is of the same length as the stent 18. See Col. 6, line 64-67. DiCaprio et al. also has a tube element 16, which the Examiner has characterized as a balloon.[2] Its preferred length is also equal to that of the balloon and stent (Col. 6, line 64-67 and Col. 11, lines 1-3). However it is indicated that it may be slightly shorter than the stent in some embodiments. (Col. 7, lines 7-14, Col. 11, lines 10-18). The purpose of the tube 16, also called a securement device, is to maintain the stent on the catheter and protect the balloon material during loading/crimping. (Col. 7, lines 1-7). The tube 16 is not expanded to implant the stent. Rather, any expansion is to hold the stent in place when moving it to the target area, where the balloon 14 alone is used to implant the stent.

Fig.1



I t is the Examiner's position that it would be obvious to combine the teachings of these two references to reach the claimed invention. First, even assuming the Examiner is right that combination of these references is suggested, what one most likely ends up with is a structure where inner and outer balloons and the stent are of substantially the same length. Miller has two balloons of substantially the same length. DiCaprio say the tube is preferably of the same length. If someone did combine these references, would be led to make both balloons of the same length. Thus, the limitation found in claims 1 and 23, "a length of the outer balloon is greater than a

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[2] This is clearly not a balloon. As described at Col. 7, lines 15-21, "tube component 16 is designed and constructed to have enough flexibility and have enough volume to no more than is necessary to compensate for recoil crimping of stent 18 and to closely accommodate (or even slightly over stress) the delivery diameter of stent 18, taking into consideration the thickness of the intervening uninflated balloon 14."

length of the stent and a length of the inner balloon is less than the length of the stent," would not be present. There is no teaching or suggestion of this feature in either reference. Only in Appellant's specification does one find this teaching and the reason for it, the prevention of dogboning. Even if one made the inner balloon shorter than the stent, the limitation of the outer balloon being longer than the stent would not be met.

Turning to the issue of a suggestion of combination and expectation of success. From the teaching in the art, there is no reason why one would use Miller's two balloon catheter with a stent. What purpose would one expect the inner balloon to perform? Only Appellant's specification gives a reason for the two balloons with a stent, and then only when the claimed lengths are present. The Examiner's statement that "*if the inner balloon expands with sufficient force and diameter to crack a hard stenosis [all before bursting], then such a force/diameter would be sufficient to apply a stent to such a region in an artery*" is unsupported conjecture. But even if it is true, what region? Surely there is no teaching of doing it in a region that will "expand the middle portion of said stent." Because the length of the inner and outer balloons is the same in Miller, were a stent mounted and sufficient pressure applied, each balloon would expand the full length of the stent.

In summary, it is clear from the discussion above that all of the criteria needed for a prima facie case of obviousness are missing. At most, what is suggested by the art is to use a balloon catheter to deliver a stent. This was admitted to be know in the specification. That is the only relevant teaching obtainable from DiCaprio. The Examiner admits that otherwise it teaches away. This suggestion of a balloon to deliver a stent does not equate to a suggestion of using the dual balloon catheter of Miller for stent delivery. There is no reason given in either reference for doing so. Specifically, there is no teaching or suggestion, other than in Appellant's specification that dual balloons (when they have the claimed length relationships) will provide an advantage, let alone prevent dogboning. Thus, there is also nothing that leads one to expect success in reaching Appellant's object. Nor should one expect success because, even when combined, the limitations of the relationship of between the lengths of the stent and the two balloons is missing.

Thus, the two independent claims 1 and 23, both of which contain the limitations discussed above, distinguish over the art and are allowable. The remaining claims depend on one of these claims and should also be allowed.

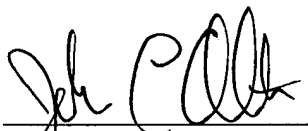
2. The dependent claims are allowable

Although all dependent claims are allowable by reason of depending on allowable claims, 2-6, 12, 24-26, and 32, further distinguish over the art. These claims were not rejected by applying prior art but simply based on the Examiner's contention that they would have been obvious. A mere contention by the Examiner is insufficient to support a rejection. Appellant is aware of no precedent that would allow this. The limitation must be found in the art. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). 'All words in a claim must be considered in judging the patentability of that claim against the prior art.' *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)." MPEP 2143.03. Nor is this a question of inherency. Appellant has selected particular pressures and pressure relationships in order to accomplish his objectives. That is, this is not a question of discovering a new function or property. It is a question of selecting materials with desired properties and using them along with the other claimed features, to provide a device that will accomplish a result of preventing dogboning.

CONCLUSION

Appellant submits that, in view of the above all claims define over the art and respectfully requests reversal of the rejections of claims 1-12 and 22-32.

Respectfully submitted,



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CLAIMS APPENDIX

1. A stent and balloon catheter in combination comprising:

a balloon catheter with an inner and an outer balloon, the outer balloon overlaying the inner balloon; and

an expandable stent mounted over the inner and outer catheter balloons,

wherein:

a burst pressure of the inner balloon is less than a burst pressure of the outer balloon, a length of the outer balloon is greater than a length of the stent and a length of the inner balloon is less than the length of the stent; and

the burst pressure of said inner balloon being such that, when inflated with a pressurized medium it will expand sufficiently to expand the middle portion of said stent and implant said stent.

2. A balloon catheter according to claim 1 wherein the burst pressure of the inner balloon is less than 10 atmospheres.

3. A balloon catheter according to claim 2 wherein the burst pressure of the inner balloon is approximately 5 atmospheres.

4. A balloon catheter according to claim 3 wherein the burst pressure of the outer balloon is greater than 10 atmospheres.

5. A balloon catheter according to claim 1 wherein the burst pressure of the inner balloon is approximately 5 atmospheres.

6. A balloon catheter according to claim 1 wherein the burst pressure of the outer balloon is greater than 10 atmospheres.

7. A balloon catheter according to claim 3 wherein the outer balloon is formed of a non-compliant material.

8. A balloon catheter according to claim 7 wherein the inner balloon is formed of a non-compliant material.

9. A balloon catheter according to claim 1 wherein the outer balloon is formed of a non-compliant material.

10. A balloon catheter according to claim 9 wherein the inner balloon is formed of a non-compliant material.

11. (original) A balloon catheter according to claim 1 wherein the catheter shaft has a guidewire port located adjacent the balloons.

12. A balloon catheter according to claim 1 wherein the burst pressure of the first balloon is at least 5 atmospheres less than the burst pressure of the second balloon.

22. A balloon catheter according to claim 1 wherein the burst pressure of said outer balloon is such that, when inflated with a pressurized medium it will expand sufficiently to expand the entire length of the stent.

23. A stent and balloon catheter in combination comprising:

a balloon catheter with an inner and an outer balloon, the outer balloon overlaying the inner balloon, both said inner balloon and said outer balloon sealed to a catheter shaft at each end;

an inflation lumen in said catheter shaft in communication only with an interior of said inner balloon; and

an expandable stent mounted over the first and second catheter balloons,

wherein:

a burst pressure of the inner balloon is less than a burst pressure of the outer balloon, a length of the outer balloon is greater than a length of the stent and a length of the inner balloon is less than the length of the stent;

the burst pressure of said inner balloon is such that, when inflated with a pressurized medium from said inflation lumen, it will expand sufficiently to expand the middle portion of said stent and implant said stent, before bursting; and

pressurized medium from said inflation lumen can enter the interior of said outer balloon to inflate it and further expand the stent over its full length only after said inner balloon bursts.

24. A balloon catheter according to claim 23 wherein the burst pressure of the inner balloon is less than 10 atmospheres.

25. A balloon catheter according to claim 24 wherein the burst pressure of the inner balloon is approximately 5 atmospheres.

26. A balloon catheter according to claim 25 wherein the burst pressure of the outer balloon is greater than 10 atmospheres.

27. A balloon catheter according to claim 24 wherein the outer balloon is formed of a non-compliant material.

28. A balloon catheter according to claim 27 wherein the inner balloon is formed of a non-compliant material.

29. A balloon catheter according to claim 23 wherein the outer balloon is formed of a non-compliant material.

30. A balloon catheter according to claim 29 wherein the inner balloon is formed of a non-compliant material.

31. A balloon catheter according to claim 23 wherein the catheter shaft has a guidewire port located adjacent the balloons.

32. A balloon catheter according to claim 23 wherein the burst pressure of the first balloon is at least 5 atmospheres less than the burst pressure of the second balloon.

EVIDENCE APPENDIX

There is no evidence presented in this appeal.

RELATED APPEALS APPENDIX

There are no other appeals, interferences, or judicial proceedings known to Appellants, appellants' legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.